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PATENT, TRADEMARK, COPYRIGHT AND UNFAIR COMPETITION LAW AND RELATED LITIGATION

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November 13, 2001 VIA HAND DELIVERY

Karin Tyson, Esquire Senior Legal Advisor United States Patent and Trademark Office Crystal Plaza 3 Washington, D.C. 20231

Term Extension of United States Patent No. 4,490,351

**VITREON®** 

Dear Ms. Tyson:

Thank you for your continued assistance in our Request for Term Extension for the above-referenced patent. We share your quest to obtain information from the Food and Drug Administration (FDA Docket No. 98E-0849), and truly appreciate your continual efforts in this regard. We, too, have been frustrated in our repeated attempts to define the problem and/or to resolve this matter satisfactorily to allow the FDA to forward the case to the United States Patent and Trademark Office.

Our understanding is that the FDA's final determination of the regulatory review period is to be republished by the FDA in the Federal Register. It is our understanding that you are in contact with Ms. Grillo at the FDA but, to date, no publication has occurred. You have also been monitoring the Federal Register. Once publication has occurred, the United States Patent and Trademark Office can then prepare a Notice of Final Determination, indicating the length of the patent term adjustment, and the information to be printed for publication in the Official Gazette.

Please let us know if our understanding is incorrect. We otherwise very much appreciate your continued assistance and updates in this matter.

Very truly yours,

Beruly A. Lyman Beverly A. Lyman, Ph.D.

BAL:cmp

Mr. Edward M. Beranek

David J. Josephic, Esquire

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